

K032092

JUL 16 2003

SMDA 510(k) SUMMARY

XCYF-TP3, Cysto-Nephrofiberscope,

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. GENERAL INFORMATION

1. Applicant

Name & Address: Olympus Optical Co., Ltd.
34-3 Hirai Hinode-machi,
Nishitama-gun, Tokyo, 190-0182, Japan
Registration Number: 3003637092

2. Initial Importer

Name & Address: Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-3157
Registration Number: 2429304

3. Submission Correspondence

Name : Masao Wada
Address : Olympus Optical Co., Ltd.
2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507,
Japan
Telephone : 81-426-42-2891
Facsimile : 81-426-42-2291
E-mail address : m_wada@ot.olympus.co.jp
Establishment Registration No. : 8010047

B. DEVICE IDENTIFICATION

1. Common/Usual Name

Cystofiberscope/ Nephrofiberscope

2. Device Name

XCYF-TP3 Cystofiberscope/ Nephrofiberscope

3. Classification Name

| CFR Number | Classification Name | Class | Product Code |
|------------|----------------------------|-------|--------------------------|
| 876.1500 | Endoscopes and accessories | II | 78KOG, 78FAJ, 78FGA, FTI |

C. IDENTIFICATION OF LEGALLY MARKED DEVICES WHICH WE CLAIM SUBSTANTIAL EQUIVALENCE

The following listed devices are seem to be as predicate devices in consideration of its characteristic and the following table shows regulatory history.

| Model | 510(k)# | Manufacturer | Class | Product Code |
|---|----------|--------------------------|-------|---|
| XCYF-1T3 OES Cystrofiberscope/ Nephrofiberscope Accessories and ancillary equipment | #K993041 | Olympus Optical Co., Ltd | II | 78FCL 78FAJ 78FGA 78KOG 78FDI 78KGE 78KNS |
| XENF-DP Laryngofiberscope, its Accessories and ancillary Equipment | #K011869 | Olympus Optical Co., Ltd | II | EOB |

D. DEVICE DESCRIPTION

1. Summary

The subject device, the XCYF-TP3 is basically identical to the predicate device (XCYF-1T3) which is the flexible endoscope for use in the bladder, urethra and kidney.

Subject device may be used with three different Light source as follow;

- A rechargeable powered Miniature Light source, or,
- A battery powered Miniature Light source as predicate device, XENF-DP, or,
- Light guide cable as predicate device, XENF-DP.

In conclusion, this subject device is technically the same as the predicate device, which we describe in the table above.

2. Design

XCYF-TP3 has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC60601-1, IEC60601-1-1and IEC60601-2-18.

3. Materials

All the patient contacting materials used in this endoscope and ancillary equipments are identical materials that have been cleared in the past 510(k) submissions. And all materials have been confirmed with ISO 10993-1.

4. Intended Use of the device

This instrument has been designed to be used with the OLYMPUS Light source, Documentation equipment, Display monitor, Endo-Therapy Accessories and other Ancillary Equipment for endoscopic diagnosis and treatment.

5. Summary including conclusion drawn form Non-clinical Tests

When compared to the preamendment/predicate device, XCYF-1T3 does not incorporate any significant changes in the intended use, method of operation, material, or designed that could affect the safety effectiveness. Therefore, the clinical data is not necessary for its evaluation of safety and efficacy.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus America, Inc.
c/o Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Systems NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

JUL 16 2003

Re: K032092

Trade/Device Name: Olympus XCYF-TP3 Cystofiberscope/Nephrofiberscope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: I
Product Code: 78 FCL
Regulatory Class: II
Product Codes: 78 FAJ, FGA, KOG
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Codes: 78 FDI, KGE, KNS
Dated: July 3, 2003
Received: July 7, 2003

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

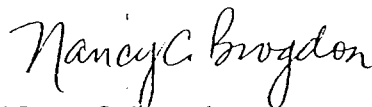
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|----------------------------------|----------------|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number(if known): K032092
~~Not assigned yet~~

Device Name: XCYF-TP3 CYSTOFIBERSCOPE/NEPHROFIBERSCOPE

Indications for Use:

This instrument has been designed to be used with an Olympus Light Source, documentation equipment, display monitor, suction pump, Endo-Therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032092